UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ADRIAN HEILBUT, JESSE BRODKIN, and ENEA MILIORIS,

Plaintiffs,

v.

CASSAVA SCIENCES, INC., REMI BARBIER, and LINDSAY BURNS,

Defendants.

Case No. 1:24-cv-05948-JLR-OTW

FIRST AMENDED COMPLAINT

JURY TRIAL DEMANDED

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Plaintiffs Dr. Adrian Heilbut, Dr. Jesse Brodkin, and Dr. Enea Milioris ("Plaintiffs"), by and through their undersigned attorneys, Clarick Gueron Reisbaum LLP, bring this action against Defendants Cassava Sciences, Inc. ("Cassava"), Remi Barbier, and Dr. Lindsay Burns (collectively, "Defendants"), and allege as follows:

NATURE OF THE ACTION

1. Plaintiffs bring this action to recover damages caused by Defendants' prosecution of a baseless defamation lawsuit against them in retaliation for their public criticism of the scientific and clinical research underlying Cassava's experimental Alzheimer's drug simufilam.

2. Plaintiffs are scientists and investors who were early and prominent critics of Cassava's scientific claims related to simufilam. Beginning in 2021, in numerous public forums, they published concerns about the implausibility of the drug's supposed mechanism of action, anomalies in research suggestive of data manipulation or fabrication, irregular results in clinical trials, and Cassava's misleading or incoherent public statements.

3. Today, Plaintiffs' criticisms have been corroborated by investigations by the Food and Drug Administration, the Department of Justice, the Securities and Exchange Commission, and the City University of New York. As a result of those investigations, Cassava's lead research collaborator Dr. Hoau-Yan Wang has been indicted, Cassava's former CEO Remi Barbier and former lead in-house scientist Dr. Lindsay Burns have been forced out of the company and barred from serving as officers or directors of public companies, and Cassava itself has accepted a $40 million fine that its new CEO Rick Barry recently described as "staggering." Based on the findings of these investigations, compounded by long-running concerns about simufilam's underlying science and research, numerous scientists and patient advocates have now called for the suspension of ongoing clinical trials of simufilam.

4. But those outcomes were not inevitable when Plaintiffs began their public criticism of Cassava and its scientific claims. Rather, Cassava and its principals, led by Barbier and Dr. Burns, battled aggressively to suppress public and scientific scrutiny of simufilam and to protect their ongoing scheme—which included raising hundreds of millions of dollars from the sale of stock to the public.

5. Defendants' intimidation campaign was intended to stifle criticism, evade scrutiny, inflate Cassava's stock, and distract from known problems with simufilam, including the lack of original data or records from its foundational experiments and studies, and the egregious research misconduct by its co-inventors and lead scientists, the now-indicted Dr. Wang and now-disgraced Dr. Burns.

6. The defamation lawsuit against Plaintiffs was a centerpiece of Defendants' effort to suppress criticism and conceal misconduct. It was designed to retaliate against Plaintiffs and their co-defendants by imposing crushing litigation costs on them and damaging their professional and personal reputations. Equally important, it demonstrated to other potential critics that Defendants would not hesitate to do the same to them.

7. For a time, Defendants' intimidation campaign worked. A major academic publisher admitted in writing that it was afraid to take action with respect to challenged research while the defamation lawsuit was pending. An expert consultant withdrew from participating in a CUNY investigation as a result of legal threats. And CUNY itself bowed to Defendants' pressure campaign by "pausing" an already completed investigation when Defendants launched spurious attacks on its integrity after its conclusions—severely critical of Dr. Wang and Dr. Burns—were published.

8. There is no real doubt about Defendants' bad faith in commencing and continuing the defamation action. The lawsuit's facial deficiencies as a matter of law were laid bare in a series of clear and thorough decisions by the Magistrate Judge and District Judge assigned to it. Its underlying factual infirmity also stands out clearly from the results of government, academic, and internal investigations that have now become public.

9. For one thing, Plaintiffs' supposedly defamatory statements are now widely recognized as substantially true: simufilam's key preclinical data *were* fabricated (according to the DOJ), the Phase 2b biomarker data *were* manipulated by Dr. Wang with the help of Dr. Burns (according to the SEC), and the Phase 2b cognitive data *were* manipulated by Dr. Burns (according to the SEC).

10. Moreover, the SEC, FDA, CUNY, DOJ—and Cassava itself—have each determined that Dr. Wang failed to retain original data or records from simufilam's foundational experiments and studies conducted at his CUNY laboratory, meaning that Defendants commenced the defamation lawsuit without evidence necessary to refute Plaintiffs' supposedly defamatory claims that the data (as presented by Dr. Wang, Dr. Burns, Barbier, and Cassava) appeared to be manipulated or fabricated. Cassava's entire business and scientific endeavor depended on that data. It owned (or, at minimum, had the right to access) the data supposedly stored at CUNY. The only possible conclusion is that Cassava, Barbier, and Dr. Burns either knew or deliberately chose not to find out that the data did not exist.

11. Indeed, the SEC has now revealed that, in a confidential internal investigation completed two months *before* Defendants commenced the defamation lawsuit against Plaintiffs, Defendants found a "lack of experiment logbooks/notebooks for all study/research work being

performed" by Dr. Wang and concluded that his lab was "unacceptable" and "not qualified to provide biomarker analysis."

12. Defendants prosecuted the defamation action in bad faith from beginning to end.

13. As a result of the lawsuit, Plaintiffs have been forced to incur substantial legal expenses, lost meaningful business opportunities, and suffered significant additional economic and non-economic harm.

14. Cassava's lawsuit and intimidation campaign have also seriously harmed the public by stifling legitimate scientific and popular discourse related to simufilam and Alzheimer's research.

15. Accordingly, Plaintiffs seek to recover their costs and attorney's fees, other compensatory damages, and punitive damages against Cassava, its former CEO Remi Barbier, and its former lead scientist Dr. Lindsay Burns.

PARTIES AND JURISDICTION

16. Plaintiff Dr. Jesse Brodkin is a citizen of New Jersey.

17. Plaintiff Dr. Adrian Heilbut is a citizen of New York.

18. Plaintiff Dr. Enea Milioris is a citizen of Greece.

19. Defendant Cassava is a publicly traded corporation incorporated in Delaware with its principal place of business in Austin, Texas, and thus a citizen of Delaware and Texas.

20. Defendant Remi Barbier is a citizen of Texas.

21. Defendant Dr. Lindsay Burns is a citizen of Texas.

22. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000 exclusive of interest and costs, and complete diversity of citizenship exists between Plaintiffs and Defendants.

23. This Court has personal jurisdiction over Cassava because this action arises out of Cassava's filing and prosecution of its lawsuit against Plaintiffs, denominated *Cassava Sciences, Inc. v. Bredt*, et al., No. 22-cv-09409-GHW-OTW (S.D.N.Y.) (the "Defamation Action"), in New York.

24. This Court has personal jurisdiction over Barbier and Dr. Burns because this action arises out of the Defamation Action initiated and prosecuted in New York at their direction and under their supervision.

25. Barbier and Dr. Burns have each purposefully and personally engaged in conduct in New York related to the transactions underlying this action, including through their control over the prosecution of the Defamation Action, their roles as Cassava's primary actors and spokespersons concerning the Defamation Action, their identification by Cassava as its principal witnesses in the Defamation Action, and their contacts with CUNY and Dr. Wang in New York.

26. The Defamation Action was initiated and continued with Barbier's and Dr. Burns's knowledge and consent, and for their personal benefit, as it was an integral part of Defendants' bad-faith intimidation campaign designed to distract attention away from their own misconduct, stifle legitimate public criticism, defend themselves against scrutiny from scientific, regulatory, and law enforcement bodies, and inflate the value of their Cassava stockholdings, which, in turn, increased their compensation from the company.

27. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims—namely, the filing and prosecution of the Defamation Action—occurred in this District.

FACTS

A. Barbier, Dr. Burns, Dr. Wang, and Cassava Repurpose Simufilam From a Supposed Painkiller to a Supposed Alzheimer's Treatment

28. Today, Cassava is the sponsor of clinical studies of an experimental new drug—simufilam—proposed to treat patients with Alzheimer's disease.

29. Cassava's claims about simufilam are based on a two-decade long research partnership between Dr. Wang, a professor at CUNY, and Dr. Burns, Cassava's former SVP of Neuroscience. (Dr. Burns is also married to Barbier, Cassava's former CEO.)

30. Cassava was founded by Barbier in 1998, under the name Pain Therapeutics, to develop painkillers based on a hypothesized benefit of "ultra-low doses" of opioid antagonists (*e.g.*, naloxone or Narcan) combined with opioids (*e.g.*, morphine).

31. Between 2006 and 2009, Dr. Wang and Dr. Burns published two (now-retracted) papers ostensibly finding that opioid antagonists, like naloxone, have additional functions mediated by binding to a protein called filamin-A.

32. In 2009, Dr. Burns and Dr. Wang filed the first patent application for what would later become simufilam, describing the compound as a painkiller, like morphine, with the novel ability to bind to filamin-A.

33. Starting in 2012, Dr. Burns and Dr. Wang formulated an entirely new hypothesis concerning simufilam. They abandoned the notion that simufilam was a painkiller, and instead suggested that it could treat Alzheimer's disease by binding to filamin-A.

34. In 2017, Dr. Burns and Dr. Wang extended their hypothesis with the unprecedented claim that Alzheimer's disease was associated with a misfolded conformation of filamin-A, and that simufilam could restore the filamin-A to its native shape.

35. In 2017, the company filed an investigational new drug application to attempt to prove that simufilam could mitigate the progress of Alzheimer's disease. The company also applied for and received NIH grants based on Dr. Burns' and Dr. Wang's claims.

36. Meanwhile, Pain Therapeutics had repeatedly failed to obtain FDA approval for pain-related drugs and formulations.

37. In 2019, after the FDA rejected its opioid formulation Remoxy for the fourth time (and publicly chastised the company for improper promotion without approval), Pain Therapeutics rebranded as Cassava and fully pivoted from opioids to focus exclusively on Alzheimer's disease.

38. Cassava raised hundreds of millions of dollars for this effort and ultimately enrolled hundreds of people in its Phase 1, Phase 2, and Phase 3 trials.

39. Today, Cassava continues to press forward with its Phase 3 trials—involving over 1,900 patients with mild-to-moderate Alzheimer's disease.

B. Plaintiffs Criticize the Scientific and Clinical Research Associated with Simufilam in Numerous Public Forums

40. At various points in time, scientists, investors, academic journals, and the media have all raised serious concerns about the numerous uncorroborated hypotheses underlying simufilam's claimed mechanism of action and the integrity of Dr. Wang's and Dr. Burns's research underlying it.

41. Plaintiffs are prominent among those critics. Beginning in 2021, Plaintiffs expressed criticism and concern about simufilam, Cassava, Barbier, Dr. Wang, and Dr. Burns in various public forums, including through: (1) an open letter to the FDA; (2) testimony at a public CUNY meeting; (3) a poster presented at a Clinical Trials on Alzheimer's Disease ("CTAD") conference describing experiments to test certain aspects of Dr. Burns and Dr. Wang's research;

(4) a letter to journal editors concerning research misconduct of Dr. Wang in 32 papers dating back two decades; (5) posts on the online scientific forum PubPeer; (6) posts on Twitter (now known as X); (7) three presentation decks describing problems with Cassava's claims related to simufilam and Cassava's ostensible diagnostic test for Alzheimer's disease, branded as SavaDX; and (8) a website compiling their critiques and sources at www.cassavafraud.com.

42. Plaintiffs have filed several FOIA and FOIL requests for information related to Dr. Wang, Dr. Burns, Barbier, simufilam, and Cassava, and have made public many previously undisclosed documents, including emails illustrating defects in the Phase 2 clinical trial design and execution.

C. Defendants File the Defamation Action to Punish and Suppress Plaintiffs' Participation in Public Discourse Concerning Simufilam

43. Since concerns first emerged about simufilam and Cassava, the company, led by Barbier and Dr. Burns, has responded by attacking its critics rather than engaging in legitimate scientific discourse or admitting the truth.

44. Defendants began to target and threaten Plaintiffs shortly after they began to speak publicly about simufilam.

45. For example, in December 2021, Dr. Burns threatened Plaintiffs and other critics in a Facebook post that stated, in part: "Sorry Adrian Heilbut. Sorry Jesse Brodkin. . . . Your days are numbered."

46. Ultimately, in an effort to punish and suppress Plaintiffs' participation in the public and scientific discourse concerning Cassava and simufilam, Defendants commenced the Defamation Action on November 2, 2022, six days after Barbier announced the hiring of a new general counsel, who would report directly to him and whom Barbier touted as a "critical addition" to Cassava's "strategic initiatives." Following through on Dr. Burns's explicit threat

against Plaintiffs, Cassava commenced the Defamation Action at the direction of Dr. Burns and Barbier.

47. In addition to Plaintiffs, Cassava named as defendants in the Defamation Action other prominent skeptics, including Dr. David Bredt, a neuroscientist and former executive at Eli Lilly and Johnson & Johnson; Dr. Geoffrey Pitt, a cardiologist at Weill Cornell Medicine; and an investment management firm, Quintessential Capital Management LLC ("QCM").

48. In the Defamation Action, Cassava alleged that Plaintiffs had made false and defamatory statements in their letter to the FDA, slide decks published online, and related posts on Twitter. The initial Complaint was 184 pages long and attached 106 exhibits.

49. Cassava sought compensatory, consequential, and punitive damages against Plaintiffs and claimed that their supposedly defamatory statements caused Cassava to lose "more than $2 billion in market capitalization."

50. Two days later, Cassava filed a First Amended Complaint, making substantially similar allegations and adding only a handful of jurisdictional allegations.

51. The allegations in the initial Complaint and First Amended Complaint were without basis in fact or law, for numerous reasons. Among many other defects in the Defamation Action, evident from the face of Cassava's pleadings:

a. Cassava made no coherent or specific allegations to support an inference of actual malice, as required under New York law, instead relying on the same set of voluminous but generic assertions of actual malice against all seven defendants in the Defamation Action.

b. The statements by Plaintiffs that Cassava attacked as "defamatory" were statements of opinion and therefore not actionable under New York law.

c. The challenged statements also constituted nonactionable scientific discourse under *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013).

d. Cassava failed to allege facts sufficient to prove falsity.

52. In addition to these facial pleading defects, the Defamation Action could never have been supported by evidence that would have shown any statement by Plaintiffs to be false. This is because (as discussed in greater depth below) the biochemical and clinical research underlying Defendants' claims about simufilam were tainted by egregious research misconduct and Defendants' lacked the original data or records from that research necessary to refute Plaintiffs' supposedly defamatory statements.

D. Defendants Ultimately Lose (and Abandon) the Defamation Action

53. On November 7, 2022, the Defamation Action was assigned to Magistrate Judge Ona T. Wang for all pre-trial purposes.

54. In early 2023, Plaintiffs' counsel conferred with Cassava's counsel—as required by Judge Wang's Individual Rules—to notify them of the bases for Plaintiffs' anticipated motion to dismiss and to afford Cassava the opportunity to avoid the burden and expense of motion practice by withdrawing or further amending the First Amended Complaint. Cassava refused to do either.

55. The other defendants held analogous discussions with Cassava, and Cassava similarly refused to withdraw the First Amended Complaint as to them.

56. Thereafter, all three groups of defendants in the Defamation Action filed motions to dismiss the First Amended Complaint: on January 6, 2023 (Drs. Bredt and Pitt), February 6, 2023 (QCM), and March 9, 2023 (Plaintiffs).

57. On February 22, 2023, Cassava identified Barbier and Dr. Burns at the top of its list of employees with first-hand knowledge about the subject matter of the Defamation Action,

including on the "development and testing of simufilam," the supposed "falsity" of Plaintiffs' statements, and Cassava's purported "damages."

58. On March 8, 2023, Magistrate Judge Wang held an Initial Pretrial Conference in the Defamation Action and ordered—over Cassava's vociferous objections—that all discovery be stayed.

59. In July 2023, Cassava served document subpoenas on Dr. Heilbut and Dr. Brodkin, ostensibly in connection with a separate consolidated securities class action that Cassava is defending in the Western District of Texas, denominated *In Re Cassava Sciences, Inc. Securities Litigation*, No. 21-cv-00751-DAE (W.D. Tex.) (the "Securities Action"). These subpoenas sought 49 broad categories of irrelevant documents, including extensive and disproportionate third-party discovery concerning Dr. Heilbut's and Dr. Brodkin's personal, professional, and financial circumstances. The subpoenas were a manifest effort to circumvent the stay of discovery entered in the Defamation Action, in a further effort to harass, punish, and intimidate Plaintiffs. Dr. Heilbut and Dr. Brodkin served timely objections to the subpoenas and, through counsel, have held multiple meet and confers with Cassava, which has refused to drop or narrow the subpoenas. In fact, Defendants most recently threatened to enforce the subpoenas while simultaneously seeking to stay discovery in the Securities Action—further demonstrating their ulterior and illegitimate use of the subpoenas.

60. On January 3, 5, and 23, 2024, Magistrate Judge Wang issued three Reports and Recommendations recommending that Cassava's claims against all three sets of defendants be dismissed. *Cassava Sciences, Inc., v. Bredt, et al.*, No. 22-cv-9409, 2024 WL 555484 (S.D.N.Y. Jan. 3, 2024); *Cassava Sciences., Inc. v. Heilbut*, No. 22-cv-9409, 2024 WL 553806 (S.D.N.Y.

Jan. 5, 2024); *Cassava Scis., Inc. v. Quintessential Cap. Mgmt. LLC*, No. 22-cv-9409, 2024 WL 554042 (S.D.N.Y. Jan. 23, 2024).

61. Cassava filed meritless objections to each of Magistrate Judge Wang's Reports and Recommendations, and each set of defendants in the Defamation Action filed responses to Cassava's objections.

62. On March 28, 2024, the Hon. Gregory H. Woods granted all defendants' motions to dismiss the First Amended Complaint. *Cassava Sciences, Inc. v. Bredt, et al.*, No. 22-cv-9409, 2024 WL 1347362 (S.D.N.Y. Mar. 28, 2024).

63. Both Judge Woods and Magistrate Judge Wang criticized Cassava's pleading tactics.

64. Judge Woods observed that Cassava had attached "dozens of studies" to its First Amended Complaint, while leaving it to the Court to "determine" whether they "conflict[] with Defendants' critiques," and failing to "direct the Court to any specific sections of the articles." *Cassava Sciences, Inc. v. Bredt, et al.,*, No. 22-cv-9409, 2024 WL 1347362, at *27 n.48 (S.D.N.Y. Mar. 28, 2024).

65. Similarly, Magistrate Judge Wang noted that Cassava's conclusory assertions, coupled with a pleading "that attaches and incorporates more than 100 exhibits (many of which contain multiple links) and spans nearly 1600 pages, is tantamount to dropping all of the scientific discourse – spanning years of research – in the lap of a randomly selected federal judge." *Cassava Sciences, Inc., v. Bredt, et al.*, 22-cv-9409, 2024 WL 555484, at *11 (S.D.N.Y. Jan. 3, 2024).

66. In fact, Magistrate Judge Wang took the unusual step of recommending dismissal of the Defamation Action on the alternative basis that its prolixity and incoherence violated Rule

8 of the Rules of Civil Procedure, requiring a plaintiff to set forth a "short and plain" statement of the claim showing that the pleader is entitled to relief. *See Cassava Sciences, Inc., v. Bredt, et al.*, 22-cv-9409, 2024 WL 555484, at *11 (S.D.N.Y. Jan. 3, 2024); *Cassava Sciences., Inc. v. Heilbut*, No. 22-cv-9409, 2024 WL 553806, at *6 (S.D.N.Y. Jan. 5, 2024).

67. Judge Woods agreed that Cassava's pleading violated Rule 8. *Cassava Sciences, Inc. v. Bredt, et al.,*, No. 22-cv-9409, 2024 WL 1347362, at *27 n.48 (S.D.N.Y. Mar. 28, 2024).

68. Defendants' abusive pleading tactics go beyond mere sloppiness; they demonstrate an objective of harassing Plaintiffs and increasing the burden and costs required to secure the inevitable dismissal of Defendants' baseless claims.

69. Following dismissal of the First Amended Complaint, Cassava filed a Second Amended Complaint against Plaintiffs, attempting to revive its claims as to a relatively smaller set of allegedly defamatory statements and purporting to cure its previous failure to plead "actual malice." Once again, Cassava sought compensatory, consequential, and punitive damages, claiming that Plaintiffs had caused "the loss of more than $2 billion."

70. The Second Amended Complaint was as baseless as the First Amended Complaint. It contained essentially no new content, instead elaborately repackaging and reordering the same allegations that had already been found insufficient to plead actual malice by Judge Woods and Magistrate Judge Wang.

71. Notwithstanding the cautionary language used by Judge Woods and Magistrate Judge Wang, Defendants repeated the same abusive pleading tactics with the Second Amended Complaint.

72. For example, the Second Amended Complaint attempted to plead actual malice by asserting 34 facts that supposedly contradicted the Plaintiffs' challenged statements, but rather

than plead the basis of any specific ostensible fact, Cassava merely referred generically to "the sources referenced above"—an oblique reference to the pleading's 569 preceding paragraphs and 192 exhibits. (SAC ¶¶ 570-604).

73. Defendants' overarching bad-faith approach was mirrored even in the most mundane aspects of their litigation practice.

74. For example, Cassava refused to agree to Plaintiffs' request for an extension of time and page limit to respond to the Second Amended Complaint—notwithstanding its egregious prolixity. Plaintiffs were left to seek such relief from the Court, which immediately granted it.

75. On June 17, 2024, Plaintiffs' counsel again conferred with Cassava's counsel, pursuant to Magistrate Judge Wang's Individual Rules, in order to explain the bases for Plaintiffs' anticipated motion to dismiss the Second Amended Complaint and to afford Cassava the opportunity to avoid the burden and expense of motion practice by withdrawing the Second Amended Complaint. Cassava again refused.

76. On June 28, 2024, Plaintiffs moved to dismiss Cassava's Second Amended Complaint.

77. On the same day, the United States Department of Justice announced the indictment of Dr. Wang for "engag[ing] in a scheme to fabricate and falsify scientific data in grant applications made to [the National Institutes of Health] on behalf of himself and [Cassava]."

78. On July 1, 2024, Cassava disclosed in a Form 8-K filed with the SEC that Cassava had been engaging with the U.S. Department of Justice and the SEC "in connection with ongoing investigations into the Company and two senior employees of the Company."

79. On July 17, 2024, Cassava announced that Barbier and Dr. Burns were departing from the company.

80. Cassava's opposition to Plaintiffs' motion to dismiss the Second Amended Complaint was due on August 2, 2024. Instead of opposing the motion, Cassava filed a notice of voluntary dismissal that day.

81. Cassava did not appeal the dismissal of its claims against any of the defendants in the Defamation Action.

82. The clarity and decisiveness with which the District Court dismissed the First Amended Complaint, and Cassava's repetition of the same inadequate factual allegations and legal theories in the Second Amended Complaint, demonstrate that the Defamation Action was commenced and continued without a substantial basis in fact or law and for the sole purpose of harassing, intimidating, punishing, or otherwise maliciously inhibiting the free exercise of speech, petition or association rights.

E. Notwithstanding its Eventual Dismissal by the Court and Abandonment by Defendants, the Defamation Action Succeeded in Suppressing Independent Scientific Review of Simufilam

83. For a time, Defendants' strategy of intimidation succeeded.

84. For example, Elsevier, Inc., which publishes numerous scientific journals, initially claimed to be investigating research misconduct associated with articles by Dr. Wang and Dr. Burns published in *Neuroscience* and *Neurobiology of Aging*. However, shortly after the Defamation Action was filed, Elsevier indicated through its in-house counsel that it would take no further action with respect to the challenged articles in light of the Defamation Action: "As I'm sure you understand, Elsevier would like to stay neutral in this dispute and would be hesitant to take action on the article while the case is still ongoing."

85. On information and belief, other journals likewise have refrained from taking such actions out of fear that they too would become victims of Defendants' penchant for retaliation.

86. CUNY also succumbed to Defendants' intimidation tactics.

87. On October 12, 2023, *Science* published a "final" copy of a 50-page report from CUNY's approximately 10-month investigation of Dr. Wang, which concluded that Dr. Wang had engaged in "egregious misconduct."[1]

88. Specifically, the CUNY investigation committee concluded that at least 20 of Dr. Wang's papers, including papers co-authored by Dr. Burns, contained "evidence highly suggestive of deliberate scientific misconduct by Dr. Wang." The only reason the CUNY investigators were unable to definitively prove their suspicions was because of "long-standing and egregious misconduct in data management and record keeping by Dr. Wang." The committee explained that it was their "intention to examine all primary data" at issue, but "[i]n no instance did Dr. Wang provide any material that could be reasonably recognized as original," Dr. Wang had failed to retain any "data that can be verified as unmanipulated," and "Dr. Wang's failure to store original data and research records represents a major break from the standards of the scientific community"—meaning, in effect, that he had destroyed the evidence of Defendants' misconduct.

[1] Defamation Action at Dkt. 101-2, "City University of New York Final Investigation Report of Associate Professor Hoau-Yan Wang, Ph.D.," (published by *Science* on October 12, 2023), https://www.science.org/do/10.1126/science.adl3444/full/cuny_wang_final_report-1698701360173.pdf

89. For multiple papers co-authored by Dr. Burns, the CUNY committee observed that Dr. Burns, as senior author, "likely bears a measure of responsibility for the integrity of the publication and the management of its underlying data."

90. Defendants responded to *Science's* publication of the CUNY report—not by defending Dr. Wang, Dr. Burns, or Cassava's lack of data—but by attacking the CUNY investigation itself on spurious grounds, including by attempting to blame the investigation and its findings on Plaintiffs and other short sellers, despite Barbier himself having previously called for the investigation and publication of its findings. Within days, CUNY announced that it had "paused" its review of Dr. Wang (which in truth was already completed) and declined to formally publish its final report even though CUNY had already sent it to the Office of Research Integrity at the U.S. Department of Health and Human Services.

91. Defendants knew that a "pause" in CUNY's investigation would have the desired effect of preventing further retractions of the published research underlying simufilam, because multiple academic journals had said they were awaiting the results of CUNY's investigation before taking further corrective actions.

92. CUNY's report concluded that "editorial action" was required with respect to 22 instances of apparent data manipulation in papers by Dr. Wang and/or Dr. Burns; however, by forestalling any "official" publication of CUNY's report, Defendants succeeded in forestalling editorial actions that would have further discredited simufilam's underlying research.

93. Moreover, CUNY's report itself describes the chilling effect of Defendants' intimidation campaign. For example, according to the report, CUNY retained an independent image consultant to examine the publications and materials provided by Dr. Wang, but after

three months of work, the consultant "precipitously withdrew their services, citing legal risks to themselves and their business."

94. All told, the Defamation Action and Defendants' campaign of intimidation have stifled legitimate public debates over Alzheimer's research, while causing significant harm to the public, including Alzheimer's patients and their families, the scientific community, and public trust in legal, regulatory, and scientific institutions.

F. Defendants' Illegitimate Purposes Are Demonstrated by Their Frivolous Claims, Bad-Faith PR Strategy, Abusive Litigation Tactics, and Public Threats

95. In addition to the facial deficiencies of the three complaints Cassava filed in the Defamation Action, Defendants' illegitimate purpose to harass, intimidate, punish, and maliciously inhibit public participation in scientific and popular discourse related to simufilam is evident from their pattern of related bad-faith conduct.

i. Defendants' PR Campaign to Blame All Bad News on Short Sellers and Shame Critics for Hurting Alzheimer's Patients

96. When Plaintiffs and other critics began to expose the reality that simufilam was based on implausible science and manipulated or fabricated research, Defendants knew they could not convincingly address the substance of Plaintiffs' critiques. Instead, Cassava, led by Barbier and Dr. Burns, concocted a conspiracy theory alleging that short sellers had made up false claims of data manipulation against Dr. Wang for their own profit and to the detriment of Alzheimer's patients. For years, Defendants have blamed virtually every negative development plaguing simufilam on this so-called "short-and-distort" scheme—including the investigations by CUNY, the SEC, the DOJ, and scientific journals. At the same time, Defendants have sought to shame their critics into silence for jeopardizing the development of Cassava's supposedly promising new Alzheimer's drug—repeatedly invoking the suffering of Alzheimer's patients as a tool to suppress further criticism.

97. The Defamation Action was a centerpiece of Defendants' "blame-and-shame" strategy, which involved attacking the motives of critics to distract from the truth of their critiques, while shaming other would-be critics into silence by casting any criticism as harmful to Alzheimer's patients in need of new treatments.

98. For example, on September 3, 2021, in response to the Citizen Petition and criticism on Twitter, Barbier claimed that Cassava was the victim of a "short and distort" campaign that was "unprecedented in its boldness, its scope, its immediacy and its intensity."[2]

99. In November 2021, in response to a *Wall Street Journal* report that the SEC was investigating claims that Cassava manipulated simufilam research results, Barbier told the paper that short sellers had lodged "outlandish accusations" against his company: "Under these conditions you would hope that someone in a position of authority is looking into the legitimacy of the allegations."[3]

100. In a *New York Times* article published in April 2022, the paper reported it had "contacted nine prominent experts for comment about the scientific underpinnings of Cassava's trials. All said they did not trust the company's methods, results or even the premise underlying the drug's supposed effectiveness."[4] In response, Barbier described the company's critics as "bad

[2] Barbier Transcript, "Public Statement Regarding Recent Allegations Against Cassava Sciences, Inc.," (Sept. 3, 2021), https://www.cassavasciences.com/static-files/d4083c4d-b4ad-4e27-a93d-edaeff13b608

[3] Dave Michaels and Joseph Walker, "SEC Investigating Cassava Sciences, Developer of Experimental Alzheimer's Drug," *The Wall Street Journal* (Nov. 17, 2021), https://www.wsj.com/articles/cassava-sciences-alzheimers-sec-investigation-11637154199

[4] Apoorva Mandavilli, "Scientists Question Data Behind an Experimental Alzheimer's Drug," *The New York Times* (Apr. 18, 2022), https://nyti.ms/3vEFVED

actors" and again blamed short-sellers for the widespread concerns of data manipulation associated with simufilam.[5]

101. On November 3, 2022, in its press release accompanying the filing of the Defamation Action, Cassava repeated false and inflammatory assertions in its pleadings, including that the "short and distort" campaign by Plaintiffs and their co-defendants "placed personal enrichment over science, over the health of patients, and over the truth"; that they "did not have any real or valid concerns with Cassava, its foundational science, or its tests"; and that their criticism was "beyond shameful."[6]

102. In the same press release, Cassava's outside counsel stated that Plaintiffs and their co-defendants had "cast a permanent cloud over research being done to try to find a treatment for a terrible disease. That is just wrong."

103. Defendants' smear campaign succeeded in impugning the credibility of Plaintiffs even among their peers within the scientific community. On November 1, 2022, just one day before Cassava filed and announced the Defamation Action, the *Journal of Clinical Investigation* published an editorial titled "Conflicting interests: when whistleblowers profit from allegations of scientific misconduct," which parroted Defendants' false accusations and attacks on Plaintiffs' integrity that Defendants had commenced in 2021. The editorial echoed Defendants' claims by portraying Plaintiffs, as well as Dr. Bredt and Dr. Pitt, as "short and distorters." And, illustrating the effectiveness of Defendants' PR campaign, the editor concluded that the academic journals'

[5] Cassava Form 8-K, "Cassava Sciences, Inc. Letter to Science Editor of the New York Times," (Apr. 26, 2022), https://www.cassavasciences.com/static-files/c45c3dde-0a21-4f68-92ed-4a894eb414e3

[6] Cassava Press Release, "Cassava Sciences Files Lawsuit Against Perpetrators of 'Short and Distort' Campaign," (Nov. 3, 2022), https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-files-lawsuit-against-perpetrators-short-and

investigations into concerns of data manipulation by Dr. Wang and Dr. Burns ought to slow down, in light of Defendants' claims that such concerns were the result of a "short-and-distort" campaign against the company.

104. Moreover, later in November 2022, in a further effort to demean Plaintiffs, Barbier submitted a letter to the editor of the *Journal of Prevention of Alzheimer's Research*, on Cassava's behalf, attacking the poster that Dr. Heilbut was then presenting at the CTAD conference. Barbier falsely accused Plaintiffs of "using adulterated simufilam," "patent infringement," and failing to disclose "conflicts of interest." Barbier included a link to the just-published *Journal of Clinical Investigation* editorial that had parroted Defendants' talking points. Barbier also cited the Defamation Action in an attempt to further leverage its frivolous claims to discredit Plaintiffs in the eyes of the scientific community.

105. On October 23, 2023, in response to *Science*'s publication of CUNY's report from its investigation of Dr. Wang, Defendants again sought to blame the "brutal, widely publicized 'short-and-distort' campaign against Cassava Sciences." Despite Barbier himself calling on CUNY to investigate Dr. Wang back in September 2021, Defendants suggested that CUNY's investigation was merely the result of short sellers' false allegations of data manipulation, and that short sellers were behind the publication of CUNY's report.[7]

106. Likewise, days after Defendants commenced the Defamation Action, Dr. Burns shared the *Journal of Clinical Investigation* editorial and Cassava's press release announcing the Defamation Action with senior NIH members over email, in an effort to neutralize the

[7] Cassava Press Release, "Statement by Cassava Sciences Regarding an Internal CUNY Report Leaked to the Press," (Oct. 13, 2023), https://www.cassavasciences.com/news-releases/news-release-details/statement-cassava-sciences-regarding-internal-cuny-report-leaked

complaints that Plaintiffs and others had submitted to the NIH about Dr. Burns and Dr. Wang's research.

107. Moreover, Defendants repeatedly and falsely described Plaintiffs as "perpetrators" of an unlawful "short and distort campaign" in the company's SEC filings from November 2022 through August 2024, despite knowing Plaintiffs' statements at issue were true.

ii. Defendants Have Engaged in Gratuitous and Abusive Litigation Practices

108. Defendants' gratuitous and abusive litigation tactics further demonstrate their ulterior and illegitimate motives for commencing and continuing the Defamation Action.

109. For example, in a further effort to humiliate Plaintiffs, Defendants chose to serve Dr. Heilbut with the Summons and Complaint in the Defamation Action in public at the CTAD scientific conference, while he was presenting Plaintiffs' poster challenging certain scientific claims by Dr. Burns, Dr. Wang, and Cassava. As illustrated below, service on Dr. Heilbut required delivery of an entire box of materials, in light of the volume of extraneous exhibits accompanying the ultimately dismissed First Amended Complaint:

110. Moreover, as detailed above, Cassava, at the direction of Barbier and Dr. Burns, filed abusive pleadings, ignored guidance provided by the Court, refused multiple opportunities to withdraw or attempt to plead viable claims when confronted with the deficiencies in its pleadings, attempted to circumvent the stay of discovery with facially improper subpoenas, and refused to afford Plaintiffs even basic courtesies expected of litigants.

iii. Defendants Have Threatened Critics, Including Plaintiffs, and Incited or Actively Encouraged Others to Repeat and Amplify Their Attacks

111. Defendants' bullying tactics have extended to all corners of the scientific community, including through efforts to silence or manipulate scientific journals, CUNY, and other individual scientists.

112. For example, Dr. Burns has sent threatening emails to other scientists who have dared to express agreement with or sympathy toward Plaintiffs. In one email to Professor Rob Howard, a clinical expert in psychiatry at University College London, on or around May 2024, Dr. Burns wrote: "Your defamatory statements will be remembered, and the world will soon decide who exactly is a Stain on the Field. I will expect a public apology."

113. Encouraged and emboldened by the Defamation Action and Defendants' strategy of attacking its critics rather than defending its research, other people have targeted Plaintiffs with increasing vitriol.

114. For example, Cassava's largest individual investor and fervent supporter, Matt Nachtrab—who repeatedly bragged online about his access to and communications with Dr. Wang and Dr. Burns—accused Plaintiffs of "genocide" and of "literally killing people" by voicing their criticisms of the science and research associated with simufilam. Moreover, an anonymous group of Cassava investors, encouraged by Defendants, sent a letter to the DOJ

petitioning it to open a criminal investigation into Dr. Bredt, Dr. Pitt, and Plaintiffs based on the same baseless allegations in the Defamation Action.

G. Defendants Knew of Fundamental Problems with the Biochemical and Clinical Research Underlying Simufilam When It Commenced the Defamation Action

115. Long before Defendants commenced the Defamation Action, they knew they would never be able to prove their claims. They knew that the science underlying simufilam was uncorroborated, novel, and controversial at best. They knew that much of simufilam's foundational research could not be verified because of long-running recordkeeping failures. They knew no original data existed to support simufilam's foundational research. And they knew that the clinical data they had publicized had been improperly manipulated and that the actual clinical data did not support their claims.

i. When They Commenced the Defamation Action, Defendants Knew Their Novel Claims About Simufilam Had Never Been Corroborated and Relied Entirely on Contested Research

116. Defendants have always known that the scientific hypotheses underlying simufilam were novel, unique to the company, and had never been independently corroborated.

117. For instance, the Cure Alzheimer's Fund, a reputable nonprofit organization committed to funding new Alzheimer's research, has summarized Defendants' claims about simufilam as follows:

> The company's core hypothesis is that when filamin-A changes its conformation, it triggers amyloid deposition, synaptic dysfunction and tau phosphorylation. The hypothesis is essentially unique to the company and its scientific founders, and the underlying science long has been challenged by the rest of the field as unable to be replicated by other labs and as inconsistent with other scientific data. In recent years, scientific sleuths and financial whistleblowers have accused the early publications supporting Cassava's hypothesis of image manipulation, and Cassava's clinical trials have been assailed for failing to follow generally accepted practices for statistical and scientific integrity. Recently, the lead scientist on the studies that led to the development of simufilam and SavaDx, Dr. Hoau-Yan Wang,

> was indicted by a federal grand jury for falsifying data to fraudulently obtain NIH grants on his own and on the company's behalf. Although Cassava points out that Dr. Wang had no part in designing the ongoing phase 3 clinical trial of simufilam, the data he allegedly falsified is the foundation of what justified the trial at all.[8]

118. The implausible and uncorroborated scientific claims by Defendants include: the high-affinity binding of naloxone to filamin-A; the high-affinity binding of simufilam to filamin-A; the patented claim that simufilam is an opioid agonist; the subsequent incongruous claim that simufilam is *not* an opioid agonist; the claim that filamin-A has a misfolded conformation associated with Alzheimer's disease; and the claim that simufilam reverts the allegedly misfolded conformation of filamin-A to its natural shape.

119. All of these claims are foundational to the mechanism of action that Defendants have proposed for simufilam. Not one of them has been corroborated by any independent scientist, accepted in the scientific community, or deployed or embraced by any other commercial or academic enterprise.

120. Even before Defendants commenced the Defamation Action, at least three scientific journals (*PLoS One*, *Alzheimer's Research & Therapy*, and *Molecular Neurodegeneration*) had retracted at least seven research papers co-authored by Dr. Burns or Dr. Wang. And at least four other scientific journals (*Neuroscience*, *Journal of Neuroscience*, *Neurobiology of Aging*, and *Physiology & Behavior*) had issued Expressions of Concern or corrections regarding at least six research papers co-authored by Dr. Wang or Dr. Burns.

121. Moreover, in response to the Citizen Petition, Barbier himself publicly admitted to certain errors in simufilam's foundational research.

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[8] Cure Alzheimer's Fund, "Updates and Insights From Our CEO," (Sept. 6, 2024), https://curealz.org/news-and-events/updates-and-insights-from-our-ceo/

122. Accordingly, prior to commencing the Defamation Action, Defendants knew that its foundational claims about simufilam were unique to the company, uncorroborated, and based entirely on contested research by Dr. Wang and Dr. Burns.

ii. When They Commenced the Defamation Action, Defendants Knew that No Original Data Existed to Support Their Scientific Claims

123. In order to show that Plaintiffs' criticisms of simufilam were defamatory, Cassava would have had to prove that—contrary to Plaintiffs' expressed beliefs—the drug's ostensible mechanism of action rested on sound scientific research.

124. However, numerous investigations have revealed that Defendants lack the original data underlying their scientific claims about simufilam.

125. Defendants knew prior to commencing the Defamation Action that no such data existed, for at least three reasons: (1) the close and ongoing collaboration between Dr. Wang and Dr. Burns; (2) Cassava's relationship with Dr. Wang and CUNY, which provided Cassava with ownership of, or access to, all research and data related to Cassava; and (3) Cassava's internal investigation completed in September 2022, which found that Dr. Wang's laboratory lacked original records or data.

126. As the Defamation Action continued, Defendants' lack of data was confirmed and corroborated repeatedly over the course of the investigations conducted by the SEC, DOJ, FDA, and CUNY.

127. Much of the missing or non-existent data concerns a research method known as Western blot analysis.

128. A Western blot is a technique used in biochemistry to observe and quantify relative amounts of proteins in a sample, by separating them according to molecular weight or charge followed by detection using antibodies that bind specifically to the protein of interest. The

end result of the technique is a film or electronic scan recording an image of a membrane (essentially a sheet of paper), on which the presence of the targeted protein is indicated by dark areas, or 'bands' where the film has been exposed to a signal generated by the detected antibodies bound to the protein. The relative amounts of proteins in a sample can be established by densitometry, which quantifies how light or dark the bands are.

129. It is standard scientific practice to save and retain the complete set of images (and if using physical film, the films themselves) associated with a Western blot, which enables later quantitative analysis and evaluation of the data in the context of controls and molecular weight markers.

130. The missing or non-existent data also concerns another common research method known as ELISA testing, which is used to detect and measure antigens, proteins, and hormones in samples such as bodily fluids. Samples are loaded onto a plate and measured by specialized equipment (ELISA plate reader), which output the results in an immutable file (plate map).

131. It is likewise standard scientific practice to save the immutable file output of the ELISA plate reader, which is the original record of the ELISA experiment.

132. As ultimately made public through investigations by CUNY, the DOJ, the FDA, and the SEC—Dr. Wang kept none of the original films or whole scanned images of any of the Western blot experiments, nor did he keep any of the original records from the ELISA tests, that he claimed to have done, including those that supposedly underpin the decades of research behind Cassava's claims about simufilam, those that would be necessary to defend simufilam's patent, and those that supposedly showed simufilam's improvement of biomarkers during clinical studies.

133. For example, Cassava's claim that filamin-A is misfolded in patients with Alzheimer's disease lies at the heart of Cassava's claims about simufilam (and its supposed diagnostic test, SavaDx).

134. The only supposed evidence that filamin-A is misfolded in Alzheimer's patients are certain Western blot experiments reported by Dr. Wang and Dr. Burns in a 2017 paper. However, according to the DOJ's indictment, Dr. Wang fabricated the Western blot images purporting to show simufilam's mechanism of action in that 2017 paper.

135. Cassava has admitted that it relied on Dr. Wang's laboratory to conduct these experiments and preserve the original data.

136. Each of the DOJ, FDA, SEC, CUNY—and Cassava itself—has now concluded that Dr. Wang failed to preserve the raw data or original records (*e.g.*, the original films or uncropped scans from Western blot experiments, or the plate reader files and audit trails from ELISA tests) from simufilam's foundational experiments and clinical studies:

a. The SEC found that, between April and September 2022, Cassava conducted its own audit of Dr. Wang's laboratory and found critical issues with the laboratory and Dr. Wang's practices, including a "lack of experiment logbooks/notebooks for all study/research work being performed"; and a "lack of procedures, proper document practices, equipment and freezer qualification, and software access control." Cassava's internal audit in 2022 concluded that Dr. Wang's laboratory was "unacceptable and temporarily not qualified to provide biomarker analysis and research services for any future Cassava studies." And, the SEC concluded

that "[b]oth Barbier and Dr. Burns were generally aware of the findings in the report" from Cassava's internal audit in September 2022.[9]

b. The DOJ found that Dr. Wang "failed to keep original scientific data"; "fabricated and falsified the results of his scientific research [], including Western blotting, such that the results were not accurately represented in the research record"; and when scientific journals requested raw, uncropped versions of the Western blot images presented in Dr. Wang's research, Cassava sent additional Western blot images fabricated by Dr. Wang.[10]

c. The FDA found that Dr. Wang's laboratory "did not maintain": "Documentation of sample storage and tracking"; "Documentation of experimental procedures"; "Source records for Western blot analysis"; or "Audit trails for the plate reader … used in ELISA assays."[11]

d. CUNY found that Dr. Wang's laboratory engaged in "long-standing and egregious misconduct in data management and record keeping"; Dr. Wang could not provide "even a single datum or notebook in response to any allegation" of data manipulation; and Dr. Wang's "inability or unwillingness to provide primary research materials to [CUNY's] investigation" was a "deep source of frustration."

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[9] Complaint, *SEC v. Cassava Sciences, Inc.,* et al., No. 24-cv-1150 (W.D. Tex. Sept. 26, 2024) at Dkts. 1 and 2-1, https://www.sec.gov/files/litigation/complaints/2024/comp-pr2024-151.pdf; Order Instituting Cease and Desist Proceedings, *In the Matter of Hoau-Yan Wang*, File No. 3-22210 (SEC Sept. 26, 2024), https://www.sec.gov/files/litigation/admin/2024/33-11311.pdf

[10] Indictment, *U.S.A. v. Hoau-Yan Wang*, No. 24-cr-211-TDC (D. Md. June 27, 2024) at Dkt. 1, https://storage.courtlistener.com/recap/gov.uscourts.mdd.562688/gov.uscourts.mdd.562688.1.0.pdf

[11] FDA Establishment Inspection Report (Sept. 16, 2022), https://www.science.org/do/10.1126/science.z7wo4zp/full/fda_cuny_inspectionreport91422to91622-1710956817103.pdf

137. Upon information and belief, Cassava's contracts with CUNY provided that Cassava was the owner of all the underlying, original data from Dr. Burns and Dr. Wang's simufilam experiments and studies (at minimum, Defendants had the right or ability to access and review the data).

138. Despite their rights to the supposed data and responsibility for it, Defendants manifestly failed to ensure that Dr. Wang or his lab at CUNY preserved it—or even to confirm that it ever existed.

139. Defendants also lied about their access to the (non-existent) data in question.

140. For example, Barbier claimed in September 2021 (in response to criticisms of Dr. Wang's Western blots) that "Cassava Sciences does not have its own laboratory facilities. We use other people's labs. For this reason, we don't have the original films or images for the Western blots in question."

141. This statement was deliberately misleading, considering Cassava either owned or was entitled to access the very data—Dr. Wang's Western blot images—that Barbier claimed it did not have.[12]

142. Moreover, as Dr. Wang's senior co-author and collaborator for two decades, Dr. Burns bears substantial responsibility for their research and recordkeeping misconduct. Dr. Burns must have known about Dr. Wang's research methods and recordkeeping practices for years and she had actual knowledge by at least September 2022 when the company's internal

[12] On the same conference call, Barbier claimed that "I have respectfully requested that CUNY inquire thoroughly but expeditiously into the allegations targeting Prof. Wang. I have also asked CUNY that its conclusionary findings be made available to the public." In retrospect, this call for an investigation is extraordinary in light of Barbier's subsequent insistence that CUNY undertook its investigation only at the prompting of corrupt short sellers—ignoring his own public request. Barbier's ostensible call for transparency also stands in contrast to Defendants' determined efforts to obstruct and discredit the CUNY investigation.

audit was completed. Likewise, Barbier, as CEO, spouse of Dr. Burns, and the company's chief spokesman responsible for responding to allegations of data manipulation, knew of Dr. Wang's research and recordkeeping misconduct since at least September 2022 and similarly bears substantial responsibility.

143. For all these reasons, even assuming original data ever existed, Defendants knew that none existed at the time they commenced the Defamation Action—meaning Defendants knew that they could never refute the allegedly defamatory claims that simufilam was based on manipulated or fabricated data—and thus knew they could never prove Plaintiffs' statements to be false or defamatory.

iii. When They Commenced the Defamation Action, Defendants Knew Simufilam's Clinical Trial Results Were Tainted by Research Misconduct

144. Prior to commencing the Defamation Action, Defendants knew that simufilam's Phase 2b study was tainted by research misconduct and that they could never refute Plaintiffs' allegedly defamatory statements critiquing that study.

145. Cassava's Phase 2b trial, which began in 2019, was to be conducted as a randomized, double-blinded study to assess certain biomarker changes over 28 days of simufilam treatment. The Phase 2b study was a critical step to generate evidence supporting simufilam as a potential treatment for Alzheimer's disease and to justify much larger confirmatory studies required for FDA approval, and to raise capital to fund those studies.

146. Cassava initially hired a laboratory at Lund University in Sweden to measure the biomarkers.

147. On May 15, 2020, Cassava issued a press release reporting that the Phase 2b data showed the drug had failed to improve levels of biomarkers of the disease. As a result, Cassava's stock lost approximately 75% of its value.

148. After the initial Phase 2b failure, Defendants devised a specious statistical argument to justify disregarding the first round of results, suggesting that the independent lab in Sweden that had analyzed patient samples (one of the best-regarded such labs in the world) did so improperly.

149. Defendants sought to "re-do" the biomarker analysis in a different laboratory, using back-up samples, and claimed that the samples would be re-tested in an independent laboratory, failing to disclose that Dr. Wang—the co-inventor of simufilam, who had been on Cassava's payroll for years, was participating in the company's bonus plan, was a member of its Scientific Advisory Board, and was obviously not "independent"—would conduct the "re-do."

150. On August 26, 2020, the Cassava Board of Directors approved a new Cash Incentive Bonus Plan, which would reward participants including Barbier, Dr. Burns, and Dr. Wang with large cash bonuses (potentially totaling $50M in aggregate) tied to increases in the company's share price and valuation.

151. In September 2020, Cassava reported the results of its "re-do" analysis. This time, simufilam appeared to dramatically improve biomarkers—and Cassava's stock nearly doubled.

152. The always suspicious results of the Phase 2b study, which were never accepted for publication by a peer-reviewed journal, have now been completely discredited.

153. Prior to commencing the Defamation Action, Defendants were aware of serious research misconduct related to the Phase 2b study, including by Dr. Burns herself.

154. On September 16, 2022, the FDA issued an inspection report of Dr. Wang's laboratory, which focused on the Phase 2b study and found that neither Dr. Wang nor CUNY had any original records or data from Dr. Wang's Western blot analysis of the Phase 2b study samples.

155. Plaintiffs obtained the FDA's inspection report through a FOIA request and it was eventually published by *Science* in March 2024. Shortly thereafter, an Editor's Note was added to the non-peer reviewed preprint of the Phase 2b study, stating: "In light of concerns about the credibility of claims by Wang and Cassava" raised by the FDA inspection report, such "challenges cannot be overlooked," and "[w]e encourage a balanced view on this preprint considering the potential benefits of the drug alongside the current investigations into Cassava Sciences' research practices."[13]

156. Cassava's internal audit of Dr. Wang's lab, conducted between April and September 2022, further demonstrated to Defendants that Dr. Wang's "re-do" analysis of the Phase 2b study was unreliable due to Dr. Wang's "unacceptable" research and recordkeeping practices.

157. Moreover, Defendants had repeatedly claimed that Dr. Wang was blinded during his "re-do" analysis of the Phase 2b study, both as to (1) whether a given sample was taken from a patient in the treatment group or the control group; and (2) whether the sample was taken before or after simufilam treatment was administered.

158. In reality, Dr. Wang and his lab were not blinded as to time-points, and Dr. Wang was not blinded with respect to treatment for a large portion of the samples, which allowed him to manipulate the results to benefit Defendants.

159. On July 1, 2024, days after the indictment of Dr. Wang, Cassava finally admitted that Dr. Wang was unblinded during his analysis of the Phase 2b study—disclosing that an internal investigation had "determined that certain statistical information contained in an

[13] Wang, H., Pei, Z., Lee, K., Rojas, Y. G., Doehner, T., Puente, J., & Burns, L. H. (2021). "Effects of simufilam on cerebrospinal fluid biomarkers in alzheimer's disease: a randomized clinical trial," https://doi.org/10.21203/rs.3.rs-249858/v1

attachment to an email sent by a senior employee of Cassava to Dr. Wang before the bioanalysis could have been used to unblind him as to some number of Phase 2b Study participants."

160. Hence, Cassava knew or should have known since at least the spring of 2020—when that email was sent—that Dr. Wang was not blinded when conducting his analysis of the Phase 2b study.

161. Even more damning is the fact that Dr. Wang was un-blinded by Dr. Burns.

162. According to the SEC's investigation, on May 14, 2020, Dr. Burns sent an email to Dr. Wang with information sufficient to unblind him to a substantial portion of study subjects.

163. Enabled by Dr. Burns, Dr. Wang then deliberately manipulated or fabricated the results of the Phase 2b study, which Defendants then touted to inflate Cassava's stock, enrich themselves, and justify further clinical trials of simufilam. According to the SEC, Dr. Wang used the information provided by Dr. Burns "to manipulate the reported results to show that patients taking the placebo had little change in biomarkers on average while patients taking [simufilam] showed significant improvement on average."

164. Defendants also deliberately misrepresented the Phase 2b study "results" concerning cognitive changes.

165. While the primary endpoints of the Phase 2b study were the biomarkers, Cassava also measured cognitive changes.

166. When the "re-do" results were announced, Cassava reported directional improvements in certain cognitive tests and claimed that cognitive improvements were correlated with improvements in biomarkers.

167. In fact, the cognitive data reported for the Phase 2b trial had been selectively reported and cherry-picked by Dr. Burns to convey a false and misleading impression that simufilam had a beneficial effect on cognition.

168. According to the SEC, Dr. Burns "failed to disclose that the spatial working memory measurement reported in the Phase 2b results as showing cognitive improvement of up to 46% was a measurement selected by Dr. Burns only after she was unblinded." At the same time, Defendants concealed the fact that "the other spatial working memory results, including measurements identified as 'key' prior to unblinding, did not show directional improvement in patients receiving [simufilam] compared with placebo."

169. Thus, today, the "results" from the Phase 2b study that Defendants announced in September 2020 have been wholly discredited. Those supposed results were a central focus of Plaintiffs' public critiques (and submissions to regulators) beginning in 2021 that Defendants claimed were defamatory in the Defamation Action.

170. The allegations in the Defamation Action were baseless because key preclinical data were fabricated (according to the DOJ), the Phase 2b biomarker data were manipulated by Dr. Wang with the help of Dr. Burns (according to the SEC), and the Phase 2b cognitive data were manipulated by Dr. Burns (according to the SEC).

171. In other words, Plaintiffs' purportedly defamatory statements in the Defamation Action were all substantially true, and Defendants knew as much from the outset of the litigation. At minimum, Defendants knew they lacked the facts necessary to prove otherwise.

H. The Defamation Action Caused Plaintiffs Substantial Damages

172. Plaintiffs were forced to incur hundreds of thousands of dollars in attorney's fees and costs in defending the Defamation Action, including but not limited to moving to dismiss the First and Second Amended Complaints.

173. Plaintiffs were also forced to incur costs in responding to the subpoenas issued by Cassava in the Securities Action, manifestly intended as an end-run around the stay of discovery in the Defamation Action.

174. Plaintiffs spent hundreds of hours managing their defense of the Defamation Action, commencing this action (and will need to spend many more hours prosecuting this action)—time they would otherwise have spent (or would otherwise spend) generating income for their respective businesses.

175. All three Plaintiffs have suffered substantial reputational harms as a result of the Defamation Action and Defendants' campaign to smear Plaintiffs as "short and distorters," which included attacks on their integrity and credibility as scientists, consultants, and investors. Defendants' attacks on Plaintiffs were echoed and reported widely across the scientific community, including in journals like the *Journal of Clinical Investigation* and *Journal of Prevention of Alzheimer's Research*, and news outlets like *Nature News* and *Biospace*—exposing Plaintiffs to widespread (and unfounded) contempt within the scientific and investment communities, while damaging their businesses and career prospects.

176. Dr. Milioris is a biopharmaceutical consultant and investment manager based in Greece. After spending several years working as a salaried and freelance consultant for biopharmaceutical companies and clinical research organizations (CROs) in London and Athens, Dr. Milioris secured an employment offer in 2022 from one of the largest drug manufacturers in Greece. Before the Defamation Action began, Dr. Milioris negotiated employment terms over

the course of several weeks and signed a three-year employment agreement in the fall of 2022, under which he would receive an annual base salary of approximately (USD) $100,000, plus a bonus of up to 40%. The contract also contained an option to renew. However, prior to his planned start date in January 2023, Defendants filed the Defamation Action. The employer terminated their agreement during an in-person meeting, expressly citing concerns about the attention and bad publicity caused by the Defamation Action.

177. In addition, Dr. Milioris experienced substantial emotional and medical disruptions and incurred significant costs associated with anxiety caused by the Defamation Action and Defendants' intimidation campaign.

178. Dr. Heilbut also suffered substantial harms. When the Defamation Action began in November 2022, Dr. Heilbut was self-employed as an investment and biotechnology consultant and worked as a part-time adjunct instructor at a university in New York. In May 2022, Dr. Heilbut was launching a new research consulting business, pivoting his career to focus on biotech equity research and investment management, while also developing software to organize and share investment research.

179. Between November 2021 and November 2022, Dr. Heilbut established new relationships with multiple top biotech and generalist hedge funds. Several of these relationships were the result of research published in collaboration with the other Plaintiffs concerning Cassava. For example, Dr. Heilbut was consulting regularly through the Guidepoint expert network platform and participated in approximately 15 calls between November 2021 and October 2022, billed at an hourly rate of $350. In the fall of 2022, Dr. Heilbut also had preliminary conversations with the client about the possibility of a more substantial and ongoing consulting engagement. However, after the Defamation Action was filed, the client explained

that it was no longer able to engage him because they feared becoming targets of discovery in the Defamation Action. As a result, Dr. Heilbut lost at least $8,500 between November 2022 and October 2024 that he would have otherwise earned from regular consulting calls—and more significantly, Dr. Heilbut lost the opportunity to enter a more lucrative and substantial consulting agreement with the client.

180. In addition to this specific loss of business, the Defamation Action and Defendants' campaign of intimidation substantially interfered in Dr. Heilbut's efforts to launch his equity research and consulting business—a business highly dependent on discretion and confidentiality in the exchange of information and analysis. The Defamation Action and Defendants' intimidation campaign chilled Dr. Heilbut's ability to freely communicate new research and opinions, and prevented him from marketing his expertise—both of which were essential to the success and growth of his new business.

181. Due to the financial pressures of the Defamation Action, the associated emotional and mental distractions, and the interference in his efforts to launch his consulting business, Dr. Heilbut has been forced to set aside his research consulting business and instead obtain full-time employment as a senior data scientist in a different industry. The damage and disruption to Dr. Heilbut's career caused by the Defamation Action have also caused substantial emotional and psychological harm.

182. Dr. Brodkin is a psychopharmacology consultant and investor, who experienced substantial harm to his professional reputation, suffered a sharp reduction in his income in 2023 and 2024 relative to 2022, and lost valuable investment opportunities worth tens of thousands of dollars, as a result of the Defamation Action. Dr. Brodkin also experienced substantial emotional and psychological harm as a result of the Defamation Action, including severe interference to his

personal relationships, due to the fear associated with being sued by a large, public pharmaceutical company and blamed for the "loss of over $2 billion"—distress compounded by Defendants' personal threats against Dr. Brodkin, their pattern of intimidation, and their escalating tactics.

COUNT ONE
(New York Civil Rights Law § 70-a)
Against Defendant Cassava

183. Plaintiffs repeat and re-allege all other Paragraphs as if set forth fully within.

184. Cassava commenced and continued the Defamation Action, which is an action involving public petition and participation, as defined in New York Civil Rights Law § 76-a.

185. All of Plaintiffs' challenged statements in the Defamation Action were made between November 2021 and March 2024, and the Defamation Action was commenced and continued from November 2022 to August 2024, after the November 10, 2020, effective date of the amendments to New York's statutory anti-SLAPP regime (N.Y. Senate Bill No. 52-A/Assembly Bill No. 5991A).

186. The Defamation Action involved claims based upon communications by Plaintiffs in places open to the public and in public forums (*e.g.*, Twitter and other websites) in connection with an issue of public interest (*e.g.*, Alzheimer's research).

187. The Defamation Action involved claims based upon lawful conduct by Plaintiffs in furtherance of the exercise of the constitutional right of free speech in connection with an issue of public interest, or in furtherance of the exercise of the constitutional right of petition.

188. The Defamation Action was commenced and continued without a substantial basis in fact and law and could not be supported by a substantial argument for the extension, modification, or reversal of existing law.

189. From November 2022 through August 2024, during the entire period that Cassava pursued the Defamation Action, Cassava lacked relevant proof that a reasonable mind could accept as adequate to support the conclusion that Plaintiffs defamed Cassava or conspired to defame Cassava.

190. The Defamation Action was commenced and continued for the sole purpose of harassing, intimidating, punishing, or otherwise maliciously inhibiting the free exercise of speech, petition or association rights.

191. Cassava commenced and continued the Defamation Action in retaliation against Plaintiffs for their public criticism of Cassava and simufilam.

192. From November 2022 through August 2024, during the entire period that Cassava pursued the Defamation Action, Cassava knew that its claims in the Defamation Action were facially deficient as a matter of law and impossible to prove.

193. Plaintiffs have suffered significant economic and non-economic damage as a result of the Defamation Action.

194. The Defamation Action and Cassava's campaign of intimidation have stifled legitimate debate over Alzheimer's research, while causing significant harm to the public at large, including Alzheimer's patients and their families, the scientific community, and public trust in legal, regulatory, and scientific institutions.

COUNT TWO
(Malicious Prosecution)
Against All Defendants

195. Plaintiffs repeat and re-allege all other Paragraphs as if set forth fully within.

196. The Defamation Action was initiated and continued by Cassava, at the direction of Barbier and Dr. Burns, who were Cassava's CEO and Senior Vice President of Neuroscience, respectively, and are married.

197. Barbier and Dr. Burns each individually participated in the malicious prosecution of the Defamation Action, including by issuing threats or attacks against Plaintiffs on Facebook, investor calls, and other forums, by participating in decisions to commence and continue the lawsuit, by publicly and privately spreading the baseless allegations in the lawsuit, by orchestrating and implementing the company's PR campaign that falsely blamed all criticism of simufilam on a "short and distort" campaign, and by overseeing the company's overall litigation strategy, which included the Defamation Action and the recruitment and hiring of a new general counsel, reporting directly to Barbier, six days before the lawsuit was filed.

198. The Defamation Action was terminated in favor of Plaintiffs, as evidenced by (i) the voluntary dismissal of the Second Amended Complaint on the deadline for Cassava's opposition to Plaintiffs' motion to dismiss, and (ii) the decision not to appeal the Court's prior dismissal of the First Amended Complaint.

199. Defendants abandoned the Defamation Action without any settlement, compromise, inducement, or consideration of any kind from Plaintiffs.

200. The Defamation Action was entirely and patently without probable cause from beginning to end.

201. Defendants knew they lacked probable cause and could never prove that Plaintiffs' supposedly defamatory statements were false or defamatory because Defendants knew that the foundational scientific claims supporting simufilam were widely contested among the scientific community and had never been independently corroborated; they also knew that they lacked original records or data capable of refuting Plaintiffs' statements that the data presented by Defendants appeared to be fabricated or manipulated; they knew from their internal audit in September 2022 that Dr. Wang's laboratory was "unacceptable" and failed to retain any original

records or data; and they knew that the clinical studies supporting simufilam were tainted by egregious research misconduct, including by Dr. Burns individually.

202. Defendants pursued the Defamation Action to retaliate against and punish Plaintiffs for raising legitimate and well-founded concerns about simufilam and Cassava.

203. The Defamation Action was a sham intended to silence, intimidate, and discredit Plaintiffs and other critics, and it was consistent with a long pattern of intimidation and coercion by Defendants, whose sole aim has been to inflate Cassava's stock price and enrich themselves, to the detriment of Plaintiffs, their investors, the scientific community, and Alzheimer's patients.

204. The Defamation Action caused special injuries to each Plaintiff, including highly substantial and identifiable interference to each Plaintiff's person, property, or business, representing concrete harms that are considerably more cumbersome than the ordinary demands of defending a lawsuit.

205. For example, as a direct result of the Defamation Action, Dr. Milioris suffered special damages to his consulting business of at least $300,000, in addition to other harms; and Dr. Heilbut suffered special damages due to the loss of his research consulting business, including at least $8,500 in hourly fees and the opportunity to enter a long-term engagement with one client, in addition to other harms.

COUNT THREE
(Conspiracy)
Against All Defendants

206. Plaintiffs repeat and re-allege all other Paragraphs as if set forth fully within.

207. Defendants knowingly, willfully, and actively conspired and agreed to commence and continue the Defamation Action and to commit Counts One and Two.

208. The Defamation Action was a central component of Defendants' concerted and coordinated PR campaign, led by Barbier and Dr. Burns, designed to silence, intimidate, and

discredit Plaintiffs and other critics, distract from problems with simufilam's foundational scientific and clinical research, evade further public and government scrutiny, conceal and cover-up their misconduct, and inflate Cassava's stock price.

209. Dr. Burns and Barbier each had personal stakes in achieving Cassava's objectives that went beyond merely carrying out the corporation's managerial policies.

210. Dr. Burns had additional, independent, and personal conspiratorial purposes, including the protection of her reputation as a scientist and as the co-author or collaborator with Dr. Wang on much of the scientific and clinical research that Plaintiffs had criticized, the concealment and cover-up of her own personal research misconduct and misrepresentations, limiting her personal exposure to civil and criminal liability, keeping her job, and inflating her compensation.

211. Barbier had additional, independent, and personal conspiratorial purposes, including, as Dr. Burns's husband, the protection of her professional and scientific reputation, the concealment and cover-up of his own misconduct and misrepresentations, limiting his personal exposure to civil and criminal liability, keeping his job, and maximizing his compensation.

212. The additional, independent interests of Barbier and Dr. Burns are further illustrated by their eventual resignations from Cassava, announced on July 17, 2024, in connection with long-running internal and government investigations—and the abandonment of the Defamation Action shortly thereafter.

213. Defendants engaged in various wrongful and overt acts in furtherance of their conspiracy, including their threats against Plaintiffs; their malicious prosecution of the Defamation Action; their public and private dissemination of the baseless allegations in the

Defamation Action; their concealment, cover-up, and suppression of facts that substantiated Plaintiffs' supposedly defamatory critiques, such as the findings of Cassava's internal audit in September 2022; their unlawful acts identified by the SEC; and their other unlawful or wrongful acts described herein.

214. As a direct and proximate result of the operation and execution of Defendants' conspiracy, Plaintiffs have suffered substantial damages.

PRAYER FOR RELIEF

WHEREFORE, Dr. Brodkin, Dr. Heilbut, and Dr. Milioris demand judgment as follows:

A) Awarding Plaintiffs' costs and attorney's fees incurred in connection with the Defamation Action;

B) Awarding Plaintiffs' costs and attorney's fees incurred in prosecuting this action;

C) Awarding Plaintiffs additional compensatory damages in an amount to be proven at trial;

D) Awarding Plaintiffs actual and special damages in an amount to be proven at trial;

E) Awarding Plaintiffs punitive damages in an amount to be established at trial;

F) Awarding Plaintiffs pre- and post-judgment interest; and

G) Any such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by a jury of twelve jurors.

Dated: October 24, 2024
New York, New York

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